IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY AND EDEN BIODESIGN, LLC.	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., ALKEM LABORATORIES LIMITED, HETERO LABS LIMITED, HETERO USA INC., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED AND ZYDUS PHARMACEUTICALS (USA) INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Allergan USA, Inc., Allergan Holdings Unlimited Company, and Eden Biodesign, LLC. (collectively, "Plaintiffs"), for their Complaint against Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Alkem Laboratories Limited, Hetero Labs Limited, Hetero USA Inc., MSN Laboratories Private Limited, MSN Pharmaceuticals, Inc., Sun Pharmaceutical Industries Limited, and Zydus Pharmaceuticals (USA) Inc. (collectively, "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Allergan USA, Inc. is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

2. Plaintiff Allergan Holdings Unlimited Company is an Irish corporation having a principal place of business at Clonshaugh Business & Technology Park, Dublin 17, Ireland.

3. Plaintiff Eden Biodesign, LLC is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940 (referred to herein, together with Allergan USA, Inc. and Allergan Holdings Unlimited Company, as "Allergan").

4. Upon information and belief, Defendant Aurobindo Pharma Ltd. is an Indian corporation having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Pharma Ltd. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its wholly owned subsidiary and agent Aurobindo Pharma USA, Inc.

5. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. is a Delaware corporation having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. (referred to herein, together with Aurobindo Pharma Ltd., as "Aurobindo") is a wholly owned subsidiary of Aurobindo Pharma Ltd. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Aurobindo Pharma Ltd.

6. Upon information and belief, Alkem Laboratories Limited ("Alkem") is a corporation organized and existing under the laws of India, having a place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai 400013, Maharashtra, India. Upon information and belief, Defendant Alkem manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

7. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2 Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India. Upon information and belief, Defendant Hetero Labs Limited manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its wholly owned subsidiary and agent Hetero USA, Inc.

8. Upon information and belief, Defendant Hetero USA, Inc. is a Delaware corporation having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Upon information and belief, Defendant Hetero USA, Inc. (referred to herein, together with Hetero Labs Limited, as "Hetero") is a wholly owned subsidiary of Hetero Labs Limited. Upon information and belief, Defendant Hetero USA, Inc. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Hetero Labs Limited.

9. Upon information and belief, Defendant MSN Laboratories Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 18 Telangana, India. Upon information and belief, Defendant MSN Laboratories Private Limited manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its wholly owned subsidiary and agent MSN Pharmaceuticals, Inc.

10. Upon information and belief, Defendant MSN Pharmaceuticals, Inc. is a Delaware corporation organized having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. Upon information and belief, Defendant MSN Pharmaceuticals,

Inc. (referred to herein, together with MSN Laboratories Private Limited, as "MSN") is a wholly owned subsidiary of MSN Laboratories Private Limited. Upon information and belief, Defendant MSN Pharmaceuticals, Inc. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of MSN Laboratories Private Limited.

11. Upon information and belief, Defendant Sun Pharmaceutical Industries Limited ("Sun") is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot. No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400. Upon information and belief, Defendant Sun Pharmaceutical Industries Limited manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

13. This is a civil action for the infringement by each of the Defendants of United States Patent Nos. 8,691,860 ("the '860 patent"), 9,115,091 ("the '091 patent"), 9,364,489 ("the '489 patent"), 9,675,587 ("the '587 patent"), 9,789,125 ("the '125 patent"), and/or 10,188,632 ("the '632 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and arises from Defendants' submission of Abbreviated New Drug Applications

("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking to commercialize generic versions of Plaintiffs' Viberzi® brand eluxadoline tablets throughout the United States, including in this judicial district, before the expiration of Plaintiffs' applicable patents.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. Each of the Defendants has participated in the preparation and/or submission of an ANDA seeking approval to market and sell a generic version of Plaintiffs' branded product, Viberzi®, and has distribution channels and plans to market and sell its generic product throughout the United States, including in this judicial district, before Plaintiffs' applicable patents expire. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

16. This Court has personal jurisdiction over Defendant Aurobindo Pharma Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA, Inc. Upon information and belief, Aurobindo Pharma Ltd. is amenable to litigating in this forum based on Aurobindo Pharma Ltd.'s conduct in multiple prior litigations in this District. For example, Aurobindo Pharma Ltd. did not contest jurisdiction in Civil Action No. 14-664

(D.I. 12), Civil Action No. 14-872 (D.I. 16), Civil Action No. 14-909 (D.I. 10), Civil Action No. 14-1203 (D.I. 9), Civil Action No. 14-1469 (D.I. 8), Civil Action No. 15-902 (D.I. 59), Civil Action No. 15-1032 (D.I. 8), Civil Action No. 16-451 (D.I. 8), Civil Action No. 18-932 (D.I. 9), or Civil Action No. 19-748 (D.I. 11).

17. This Court has personal jurisdiction over Defendant Aurobindo Pharma USA, Inc. by virtue of, *inter alia*, the fact that Aurobindo Pharma USA, Inc. is a Delaware corporation.

18. This Court has personal jurisdiction over Defendant Alkem Laboratories Limited by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Upon information and belief, Alkem Laboratories Limited is amenable to litigating in this forum based on Alkem Laboratories Limited conduct in multiple prior litigations in this District. For example, Alkem Laboratories Limited did not contest jurisdiction in Civil Action No. 19-768 (D.I. 7), Civil Action No. 18-1043 (D.I. 141), Civil Action No. 18-304 (D.I. 13), Civil Action No. 18-189 (D.I. 8), and Civil Action No. 18-89 (D.I. 13).

19. This Court has personal jurisdiction over Defendant Hetero Labs Limited by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant Hetero USA, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Defendant Hetero USA, Inc. Upon information and belief, Hetero Labs Limited is amenable to litigating in this forum based on Hetero Labs Limited's conduct in multiple prior litigations in this District. For example, Hetero Labs Limited did not contest jurisdiction in Civil Action No. 19-178 (D.I. 11), Civil Action No. 18-1996 (D.I. 12), Civil Action No. 18-1639 (D.I. 12), and Civil Action No. 18-1043 (D.I. 66).

20. This Court has personal jurisdiction over Defendant Hetero USA Inc. by virtue of, *inter alia*, the fact that Hetero USA Inc. is a Delaware corporation.

21. This Court has personal jurisdiction over Defendant MSN Laboratories Private Limited by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant MSN Pharmaceuticals, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Defendant MSN Pharmaceuticals, Inc. Upon information and belief, MSN Laboratories Private Limited is amenable to litigating in this forum based on MSN Laboratories Private Limited's conduct in multiple prior litigations in this District. For example, MSN Laboratories Private Limited did not contest jurisdiction in Civil Action No. 19-926 (D.I. 8), Civil Action No. 19-205 (D.I. 9), Civil Action No. 18-853 (D.I. 12), Civil Action No. 18-690 (D.I. 10), and Civil Action No. 18-114 (D.I. 15).

22. This Court has personal jurisdiction over Defendant MSN Pharmaceuticals, Inc. by virtue of, *inter alia*, the fact that MSN Pharmaceuticals, Inc. is a Delaware corporation.

23. This Court has personal jurisdiction over Defendant Sun Pharmaceutical Industries Limited by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Upon information and belief, Sun Pharmaceutical Industries Limited is amenable to litigating in this forum based on Sun Pharmaceutical Industries Limited's conduct in multiple prior litigations in this District. For example, Sun Pharmaceutical Industries Limited did not contest jurisdiction in Civil Action No. 19-1500 (D.I. 10), Civil Action No. 18-1765 (D.I. 13), Civil Action No. 18-1588 (D.I. 15), Civil Action No. 18-1529 (D.I. 8), and Civil Action No. 18-237 (D.I. 14).

24. This Court has personal jurisdiction over Defendant Zydus Pharmaceuticals (USA) Inc., by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is amenable to litigating in this forum based on Zydus Pharmaceuticals (USA) Inc.'s conduct in multiple prior litigations in this District. For example, Zydus Pharmaceuticals (USA) Inc. did not contest jurisdiction in Civil

Action No. 19-1501 (D.I. 9), Civil Action No. 19-1295 (D.I. 6), Civil Action No. 19-760 (D.I. 11), and Civil Action No. 19-333 (D.I. 5).

25. Venue is proper in this judicial district as to the Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

26. On April 8, 2014, the '860 patent, titled "Crystals And Process Of Making 5-({(2-Amino-3-(4-Carbamoyl-2,6-Dimethyl-Phenyl)-Propionyl]-[1-(-4-Phenyl-1H-Imidazol-2-YL)-Ethyl]-Amino}-Methyl)-2-Methoxy-Benzoic Acid," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). The USPTO issued a certificate of correction for the '860 patent on July 29, 2014. Allergan is the sole owner of the '860 patent. A copy of the '860 patent, including its certificate of correction, is attached hereto as Exhibit A.

27. On August 25, 2015, the '091 patent, titled "Crystals And Process Of Making 5-({(2-Amino-3-(4-Carbamoyl-2,6-Dimethyl-Phenyl)-Propionyl]-[1-(-4-Phenyl-1H-Imidazol-2-YL)-Ethyl]-Amino}-Methyl)-2-Methoxy-Benzoic Acid," was duly and lawfully issued by the USPTO. Allergan is the sole owner of the '091 patent. A copy of the '091 patent is attached hereto as Exhibit B.

28. On June 14, 2016, the '489 patent, titled "Crystals And Process Of Making 5-({(2-Amino-3-(4-Carbamoyl-2,6-Dimethyl-Phenyl)-Propionyl]-[1-(-4-Phenyl-1H-Imidazol-2-YL)-Ethyl]-Amino}-Methyl)-2-Methoxy-Benzoic Acid," was duly and lawfully issued by the USPTO. Allergan is the sole owner of the '489 patent. A copy of the '489 patent is attached hereto as Exhibit C.

29. On June 13, 2017, the '587 patent, titled "Opioid Receptor Modulator Dosage Formulations," was duly and lawfully issued by the USPTO. Allergan is the sole owner of the '587 patent. A copy of the '587 patent is attached hereto as Exhibit D.

30. On October 17, 2017, the '125 patent, titled "Crystals And Process Of Making 5-({(2-Amino-3-(4-Carbamoyl-2,6-Dimethyl-Phenyl)-Propionyl]-[1-(-4-Phenyl-1H-Imidazol-2-YL)-Ethyl]-Amino}-Methyl)-2-Methoxy-Benzoic Acid," was duly and lawfully issued by the USPTO. Allergan is the sole owner of the '125 patent. A copy of the '125 patent is attached hereto as Exhibit E.

31. On January 29, 2019 the '632 patent, titled "Opioid Receptor Modulator Dosage Formulations," was duly and lawfully issued by the USPTO. Allergan is the sole owner of the '632 patent. A copy of the '632 patent is attached hereto as Exhibit F.

32. Allergan Holdings Unlimited Company holds New Drug Application ("NDA") No. 206940 for Viberzi® brand eluxadoline tablets. Viberzi® is approved for the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults. The '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Viberzi®.

33. Allergan USA, Inc. is the exclusive distributor of Viberzi® in the United States.

ACTS GIVING RISE TO THIS ACTION

Count 1 – Patent Infringement by Aurobindo

34. Upon information and belief, on or before July 30, 2019, Aurobindo submitted ANDA No. 213511 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213511 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient ("the Aurobindo Generic Products"). ANDA No. 213511 specifically seeks

FDA approval to market the Aurobindo Generic Products prior to the expiration of, *inter alia*, the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

35. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Aurobindo alleges in ANDA No. 213511 that the claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Aurobindo Generic Products. On or after July 31, 2019, Allergan received a letter from Aurobindo's counsel notifying Allergan of ANDA No. 213511, including its § 505(j)(2)(A)(vii)(IV) allegations (the "Aurobindo Notice Letter").

36. Aurobindo's submission of ANDA No. 213511 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-9 of the '860 patent, claims 1-11 and 14-23 of the '091 patent, claims 1-16 of the '489 patent, claims 1-17 of the '587 patent, claims 1-13 and 16-20 of the '125 patent, and claims 1-15 of the '632 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, upon information and belief, if Aurobindo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Aurobindo Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(a), (b), and/or (c).

37. Aurobindo has infringed, *inter alia*, the identified claims under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia*, one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Aurobindo Generic

Products and the methods of using the Aurobindo Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing information will meet each and every claim element of one or more claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, either literally or under the doctrine of equivalents.

38. Upon information and belief, Aurobindo has participated in, contributed to, aided, abetted, and/or induced infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent once the Aurobindo Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

39. Upon information and belief, Aurobindo has knowledge that if it were to receive approval from the FDA to market the Aurobindo Generic Products described in ANDA No. 213511 and make the Aurobindo Generic Products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Aurobindo has knowledge of such infringement and/or such infringing use and also knows that the products described in ANDA No. 213511 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for

use in the direct infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

40. Upon information and belief, Aurobindo was aware of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent prior to the submission of ANDA No. 213511, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label and prescribing information for the Aurobindo Generic Products will induce others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe at least the '860 patent, the '091 patent, the '489 patent, and the '125 patent, and, based on Aurobindo's § 505(j)(2)(A)(vii)(IV) allegations, Aurobindo possesses the specific intent to encourage others to infringe.

41. Aurobindo's actions render this an exceptional case under 35 U.S.C. § 285.

42. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count 2 – Patent Infringement by Alkem

43. Upon information and belief, on or before August 1, 2019, Alkem submitted ANDA No. 213613 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213613 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient ("the Alkem Generic Products"). ANDA No. 213613 specifically seeks FDA approval to market the Alkem Generic Products prior to the expiration of, *inter alia*, the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

44. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Alkem alleges in ANDA No. 213613 that the claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent are invalid, unenforceable, and/or will

not be infringed by the manufacture, use, or sale of the Alkem Generic Products. On or after August 1, 2019, Allergan received a letter from Alkem's counsel notifying Allergan of ANDA No. 213613, including its § 505(j)(2)(A)(vii)(IV) allegations (the "Alkem Notice Letter").

45. Alkem did not submit any § 505(j)(2)(A)(vii)(IV) allegations for a number of patents listed in the Orange Book for Viberzi. Those unchallenged patents expire no earlier than March 25, 2028. As a result, under the Hatch-Waxman Act, Alkem cannot offer to sell or otherwise commercialize any of the generic products described in ANDA 213613 prior to March 25, 2028 regardless of the outcome of this action.

46. Alkem's submission of ANDA No. 213613 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-9 of the '860 patent, claims 1-11 and 14-23 of the '091 patent, claims 1-16 of the '489 patent, claims 1-17 of the '587 patent, claims 1-13 and 16-20 of the '125 patent, and claims 1-15 of the '632 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, upon information and belief, if Alkem commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Alkem Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(a), (b), and/or (c).

47. Alkem has infringed, *inter alia*, the identified claims under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia*, one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Alkem Generic Products and the methods of using the Alkem Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing information will meet each and every claim element of one or more claims of the '860 patent, the

'091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, either literally or under the doctrine of equivalents.

48. Upon information and belief, Alkem has participated in, contributed to, aided, abetted, and/or induced infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent once the Alkem Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

49. Upon information and belief, Alkem has knowledge that if it were to receive approval from the FDA to market the Alkem Generic Products described in ANDA No. 213613 and make the Alkem Generic Products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Alkem has knowledge of such infringement and/or such infringing use and also knows that the products described in ANDA No. 213613 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

50. Upon information and belief, Alkem was aware of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent prior to the submission of

ANDA No. 213613, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label and prescribing information for the Alkem Generic Products will induce others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe at least the '860 patent, the '091 patent, the '489 patent, and the '125 patent, and, based on Alkem's § 505(j)(2)(A)(vii)(IV) allegations, Alkem possesses the specific intent to encourage others to infringe.

51. Alkem's actions render this an exceptional case under 35 U.S.C. § 285.

52. Plaintiffs will be irreparably harmed by Alkem's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count 3 – Patent Infringement by Hetero

53. Upon information and belief, on or before July 31, 2019, Hetero submitted ANDA No. 213427 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213427 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient ("the Hetero Generic Products"). ANDA No. 213427 specifically seeks FDA approval to market the Hetero Generic Products prior to the expiration of, *inter alia*, the '587 patent and the '632 patent.

54. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Hetero alleges in ANDA No. 213427 that the claims of the '587 patent and the '632 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Hetero Generic Products. On or after July 31, 2019, Allergan received a letter from Hetero's counsel notifying Allergan of ANDA No. 213427, including its § 505(j)(2)(A)(vii)(IV) allegations (the "Hetero Notice Letter").

55. Hetero did not submit any § 505(j)(2)(A)(vii)(IV) allegations for a number of patents listed in the Orange Book for Viberzi. Those unchallenged patents expire no earlier than July 7, 2028. As a result, under the Hatch-Waxman Act, Hetero cannot offer to sell or otherwise commercialize any of the generic products described in ANDA 213427 prior to July 7, 2028 regardless of the outcome of this action.

56. Hetero's submission of ANDA No. 213427 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-17 of the '587 patent and claims 1-15 of the '632 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, upon information and belief, if Hetero commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Hetero Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '587 patent and the '632 patent under 35 U.S.C. § 271(a), (b), and/or (c).

57. Hetero has infringed, *inter alia*, the identified claims under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia,* one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Hetero Generic Products and the methods of using the Hetero Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing information will meet each and every claim element of one or more claims of the '587 patent and the '632 patent, either literally or under the doctrine of equivalents.

58. Upon information and belief, Hetero has participated in, contributed to, aided, abetted, and/or induced infringement of the '587 patent and the '632 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '587 patent and the '632 patent once

the Hetero Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

59. Upon information and belief, Hetero has knowledge that if it were to receive approval from the FDA to market the Hetero Generic Products described in ANDA No. 213427 and make the Hetero Generic Products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '587 patent and the '632 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Hetero has knowledge of such infringement and/or such infringing use and also knows that the products described in ANDA No. 213427 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '587 patent and the '632 patent.

60. Upon information and belief, Hetero was aware of the '587 patent and the '632 patent prior to the submission of ANDA No. 213427, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

61. Hetero's actions render this an exceptional case under 35 U.S.C. § 285.

62. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count 4 – Patent Infringement by MSN

63. Upon information and belief, on or before August 12, 2019, MSN submitted ANDA No. 213576 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213576 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the

active ingredient ("the MSN Generic Products"). ANDA No. 213576 specifically seeks FDA approval to market the MSN Generic Products prior to the expiration of, *inter alia*, the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

64. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, MSN alleges in ANDA No. 213576 that the claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the MSN Generic Products. On or after August 12, 2019, Allergan received a letter from MSN's counsel notifying Allergan of ANDA No. 213576, including its § 505(j)(2)(A)(vii)(IV) allegations (the "MS Notice Letter").

65. MSN did not submit any § 505(j)(2)(A)(vii)(IV) allegations for a number of patents listed in the Orange Book for Viberzi. Those unchallenged patents expire no earlier than March 25, 2028. As a result, under the Hatch-Waxman Act, MSN cannot offer to sell or otherwise commercialize any of the generic products described in ANDA No. 213576 prior to March 25, 2028 regardless of the outcome of this action.

66. MSN's submission of ANDA No. 213576 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-9 of the '860 patent, claims 1-11 and 14-23 of the '091 patent, claims 1-16 of the '489 patent, claims 1-17 of the '587 patent, claims 1-13 and 16-20 of the '125 patent, and claims 1-15 of the '632 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, upon information and belief, if MSN commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the MSN Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(a), (b), and/or (c).

67. MSN has infringed, *inter alia*, the identified claims under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia,* one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the MSN Generic Products and the methods of using the MSN Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing information will meet each and every claim element of one or more claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, either literally or under the doctrine of equivalents.

68. Upon information and belief, MSN has participated in, contributed to, aided, abetted, and/or induced infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent once the MSN Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

69. Upon information and belief, MSN has knowledge that if it were to receive approval from the FDA to market the MSN Generic Products described in ANDA No. 213576 and make the MSN Generic Products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, MSN has knowledge of such infringement and/or such infringing use and also knows that the products described in ANDA

No. 213576 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

70. Upon information and belief, MSN was aware of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent prior to the submission of ANDA No. 213576, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label and prescribing information for the MSN Generic Products will induce others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe at least the '860 patent, the '091 patent, the '489 patent, and the '125 patent, and, based on MSN's § 505(j)(2)(A)(vii)(IV) allegations, MSN possesses the specific intent to encourage others to infringe.

71. MSN's actions render this an exceptional case under 35 U.S.C. § 285.

72. Plaintiffs will be irreparably harmed by MSN's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count 5 – Patent Infringement by Sun

73. Upon information and belief, on or before July 31, 2019, Sun submitted ANDA No. 213447 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213447 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient ("the Sun Generic Products"). ANDA No. 213447 specifically seeks FDA approval to market the Sun Generic Products prior to the expiration of, *inter alia*, the '587 patent and the '632 patent.

74. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Sun alleges in ANDA No. 213447 that the claims of the '587 patent and the '632 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sun Generic Products. On or after July 31, 2019, Allergan received a letter from Sun's counsel notifying Allergan of ANDA No. 213447, including its § 505(j)(2)(A)(vii)(IV) allegations (the "Sun Notice Letter").

75. Sun did not submit any § 505(j)(2)(A)(vii)(IV) allegations for a number of patents listed in the Orange Book for Viberzi. Those unchallenged patents expire no earlier than July 7, 2028. As a result, under the Hatch-Waxman Act, Sun cannot offer to sell or otherwise commercialize any of the generic products described in ANDA 213447 prior to July 7, 2028 regardless of the outcome of this action.

76. Sun's submission of ANDA No. 213447 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-17 of the '587 patent and claims 1-15 of the '632 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, upon information and belief, if Sun commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Sun Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '587 patent and the '632 patent under 35 U.S.C. § 271(a), (b), and/or (c).

77. Sun has infringed, *inter alia*, the identified claims under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia,* one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Sun Generic Products and the methods of using the Sun Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing

information will meet each and every claim element of one or more claims of the '587 patent and the '632 patent, either literally or under the doctrine of equivalents.

78. Upon information and belief, Sun has participated in, contributed to, aided, abetted, and/or induced infringement of the '587 patent and the '632 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '587 patent and the '632 patent once the Sun Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

79. Upon information and belief, Sun has knowledge that if it were to receive approval from the FDA to market the Sun Generic Products described in ANDA No. 213447 and make the Sun Generic Products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '587 patent and the '632 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Sun has knowledge of such infringement and/or such infringing use and also knows that the products described in ANDA No. 213447 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '587 patent and the '632 patent.

80. Upon information and belief, Sun was aware of the '587 patent and the '632 patent prior to the submission of ANDA No. 213447, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

81. Sun's actions render this an exceptional case under 35 U.S.C. § 285.

82. Plaintiffs will be irreparably harmed by Sun's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count 6 – Patent Infringement by Zydus

83. Upon information and belief, on or before August 12, 2019, Zydus submitted ANDA No. 213522 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213522 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient ("the Zydus Generic Products"). ANDA No. 213522 specifically seeks FDA approval to market the Zydus Generic Products prior to the expiration of, *inter alia*, the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

84. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Zydus alleges in ANDA No. 213522 that the claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Zydus Generic Products. On or after August 12, 2019, Allergan received a letter from Zydus's counsel notifying Allergan of ANDA No. 213522, including its § 505(j)(2)(A)(vii)(IV) allegations (the "Zydus Notice Letter").

85. Zydus did not submit § 505(j)(2)(A)(vii)(IV) allegations for a number of other patents listed in the Orange Book for Viberzi. Those unchallenged patents expire no earlier than March 25, 2028. As a result, under the Hatch-Waxman Act, Zydus cannot offer to sell or otherwise commercialize any of the generic products described in ANDA No. 213522 prior to March 25, 2028 regardless of the outcome of this action.

86. Zydus's submission of ANDA No. 213522 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of, *inter alia*, claims 1-9 of the '860 patent, claims 1-11 and 14-23 of the '091 patent, claims 1-16 of the '489 patent, claims 1-17 of

the '587 patent, claims 1-13 and 16-20 of the '125 patent, and claims 1-15 of the '632 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, upon information and belief, if Zydus commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Zydus Generic Products, or induces or contributes to any such conduct, it would further infringe, *inter alia*, these claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(a), (b), and/or (c).

87. Zydus has infringed, *inter alia*, the identified claims under 35 U.S.C. § 271(e)(2)(A), and, upon information and belief, will further infringe, *inter alia,* one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Zydus Generic Products and the methods of using the Zydus Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert and prescribing information will meet each and every claim element of one or more claims of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, either literally or under the doctrine of equivalents.

88. Upon information and belief, Zydus has participated in, contributed to, aided, abetted, and/or induced infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent once the Zydus Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

89. Upon information and belief, Zydus has knowledge that if it were to receive approval from the FDA to market the Zydus Generic Products described in ANDA No. 213522 and make the Zydus Generic Products available for sale and/or use by others, *e.g.*, by doctors,

pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Zydus has knowledge of such infringement and/or such infringing use and also knows that the products described in ANDA No. 213522 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent.

90. Upon information and belief, Zydus was aware of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent prior to the submission of ANDA No. 213522, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label and prescribing information for the Zydus Generic Products will induce others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe at least the '860 patent, the '091 patent, the '489 patent, and the '125 patent, and, based on Zydus's § 505(j)(2)(A)(vii)(IV) allegations, Zydus possesses the specific intent to encourage others to infringe.

91. Zydus's actions render this an exceptional case under 35 U.S.C. § 285.

92. Plaintiffs will be irreparably harmed by Zydus's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Aurobindo has infringed the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(e)(2)(A);

B. That Alkem has infringed the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(e)(2)(A);

C. That Hetero has infringed the '587 patent and the '632 patent under 35 U.S.C. § 271(e)(2)(A);

D. That MSN has infringed the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(e)(2)(A);

E. That Sun has infringed the '587 patent and the '632 patent under 35 U.S.C. § 271(e)(2)(A);

F. That Zydus has infringed the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent under 35 U.S.C. § 271(e)(2)(A);

G. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Aurobindo's ANDA No. No. 213511 shall not be earlier than the expiration date of the last to expire of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, including any extensions or exclusivities;

H. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alkem's ANDA No. 213613 shall not be earlier than the expiration date of the last to expire of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, including any extensions or exclusivities;

I. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Hetero's ANDA No. 213427 shall not be earlier than the expiration date of the last to expire of the '587 patent and the '632 patent, including any extensions or exclusivities;

J. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of MSN's ANDA No. 213576 shall not be earlier than the expiration date of the last to expire of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, including any extensions or exclusivities;

K. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sun's ANDA No. 213447 shall not be earlier than the expiration date of the last to expire of the '587 patent and the '632 patent, including any extensions or exclusivities;

L. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Zydus's ANDA No. 213522 shall not be earlier than the expiration date of the last to expire of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and the '632 patent, including any extensions or exclusivities;

M. That Aurobindo, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Aurobindo Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

N. That Plaintiffs be awarded monetary relief if Aurobindo commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the

Aurobindo Generic Products, or any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

O. That Alkem, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Alkem Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

P. That Plaintiffs be awarded monetary relief if Alkem commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the Alkem Generic Products, or any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

Q. That Hetero, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Hetero Generic Products, and any other product that

infringes or induces infringement or contributes to the infringement of the '587 patent and/or the '632 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

R. That Plaintiffs be awarded monetary relief if Hetero commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the Hetero Generic Products, or any other product that infringes or induces infringement or contributes to the infringement of the '587 patent and/or the '632 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

S. That MSN, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the MSN Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

T. That Plaintiffs be awarded monetary relief if MSN commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the MSN Generic Products, or any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

U. That Sun, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Sun Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '587 patent and/or the '632 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

V. That Plaintiffs be awarded monetary relief if Sun commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the Sun Generic Products, or any other product that infringes or induces infringement or contributes to the infringement of the '587 patent and the '632 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

W. That Zydus, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Zydus Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

X. That Plaintiffs be awarded monetary relief if Zydus commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the Zydus Generic Products, or any other product that infringes or induces infringement or contributes to

the infringement of the '860 patent, the '091 patent, the '489 patent, the '587 patent, the '125 patent, and/or the '632 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

Y. That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

Z. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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September 13, 2019